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IN THE COURT OF APPEAL OF THE STATE OF CALIFORNIA

FIRST APPELLATE DISTRICT

DIVISION FOUR

MARVIN C. WEINSTAT et al., Plaintiffs and Appellants, v. DENTSPLY INTERNATIONAL, INC., Defendant and Respondent.	A116248 (City and County of San Francisco Super. Ct. No. CGC-04-432370)

This is an appeal from an order decertifying a class of dentists as to their causes of action under the unfair competition law (UCL)[1] and for breach of express warranty against the manufacturer of the Cavitron ultrasonic scaler (Cavitron). What prompted the decertification? An appellate court decision interpreting the Proposition 64[2] amendments to the UCL as requiring that all class members—not just the representatives—show an injury in fact. Although our Supreme Court granted review in that decision, the trial court nonetheless stood by its decertification order and denied the dentists' request for reconsideration. Recently, the state's high court issued its decision in *In re Tobacco II Cases* (2009) 46 Cal.4th 298 (*Tobacco II*). *Tobacco II* rejects the legal premises underpinning the decertification order as to the UCL claim and mandates reversal.

We must also reverse the order decertifying the class as to the breach of express warranty claims. Procedurally, the order was improper because it was rendered in the absence of new law or evidence. Substantively, the order was contrary to law because it improperly grafted an element of prior reliance onto the express warranty claims; this error infected the entire ruling as to those claims.

[1] Business and Professions Code section 17200 et seq.

[2] Proposition 64 is the voter initiative approved November 2, 2004.

I. BACKGROUND

A. *The Device; Regulatory Framework*

Respondent Dentsply International, Inc. (Dentsply) manufactures the Cavitron, a device which dentists have used for more than four decades.[3] As a class II medical device, the Cavitron comes under the purview of the Food and Drug Administration, with its sale restricted to dental professionals. The original iterations of the Cavitron predate the Medical Device Amendments of 1976 (MDA)[4] to the federal Food, Drug and Cosmetic Act.[5] Because the subsequent, post-MDA versions are substantially equivalent to the preexisting technology, the newer versions have been cleared for marketing by the Food and Drug Administration through a premarket *notification* process rather than the full premarket *approval* process. (See 21 U.S.C. § 360(k); 21 C.F.R. § 807.92(a)(3) (2009).)

The Cavitron works by expelling a pulsating water stream from the tiny hollow tip of a handpiece attached to the device by a flexible tube. The output stream helps dislodge plaque and calculus from teeth, thereby reducing the amount of scraping or scaling by the dental practitioner. Cavitrons commonly are used to clean teeth, but can also be used for root planing and debridement in treating periodontal disease.

Under the Food, Drug and Cosmetic Act, a medical device is deemed misbranded unless its labeling bears "adequate directions for use." (21 U.S.C. § 352(f)(1).) "*Adequate directions for use* means directions under which the layman can use a device safely and for the purposes for which it is intended." (21 C.F.R. § 801.5 (2009).) By definition, "adequate directions for use" cannot be prepared for prescription devices such as the Cavitron, because these devices must be used under the supervision of a licensed practitioner. However, such devices will escape the deemed designation of being "misbranded" where, among other conditions, "[l]abeling on or within the package from which the device is to be dispensed bears information for use, including indications,

[3] Dentsply acquired the product line in 1986.
[4] 21 United States Code section 301 et seq.
[5] 21 United States Code section 360c et seq.

effects, routes, methods, and frequency and duration of administration, and any relevant hazards, contraindications, side effects, and precautions under which practitioners licensed by law to administer the device can use the device safely and for the purpose for which it is intended, including all purposes for which it is advertised or represented . . . ." (*Id*., § 801.109(c).) Dentsply accomplishes this directive by providing "Directions For Use" (Directions), which it expects the dentist to read and follow in using the Cavitron.

In 1993, Dentsply revised the Directions to indicate the Cavitron's use for "root planing during surgery." The Directions for these models were in effect until their production ceased. Around 1997, new Cavitron models were introduced in which the indications were stated in broader language to encompass "[a]ll general supra and subgingival scaling applications" and "[p]eriodontal debridement for all types of periodontal diseases."

In 2003, the federal Centers for Disease Control and Prevention (CDC) issued guidelines recommending that sterile solutions be used in all oral surgical procedures. Since 1996, California dental regulations have required practitioners to use "[s]terile coolants/irrigants" for "surgical procedures involving soft tissue or bone." (Cal. Code Regs., tit. 16, § 1005, subd. (c)(15); Register 96, No. 28.) The current provision also provides that "[s]terile coolants/irrigants must be delivered using a sterile delivery system." (Cal. Code Regs., tit. 16, § 1005, subd. (c)(15).)

B. *Litigation and Discovery*

In 2004 appellants, several dentists,[6] seeking to represent a class of practitioners who purchased a Cavitron for use during oral surgical procedures on their patients, sued Dentsply, alleging a violation of the UCL and other causes of action. The operative third amended complaint includes a cause of action for breach of express warranty. The crux of the complaint is that the Directions indicate that Cavitrons can be used in oral surgery, but in fact they are unsafe for such use because the device is incapable of delivering a safe water stream during oral surgical procedures. Specifically, the complaint alleged

[6] Appellants are Marvin C. Weinstat, D.M.D.; Richard Nathan, D.M.D.; and Patricia Murray, D.M.D., Ph.D.

that the inner tubing of the Cavitron "was designed in a manner that was subject to the formation of a progressive biofilm coating of bacteria . . . which could harbor pathogens," and because the inner tubing "was incapable of being sterilized before or during its use," bacteria would be released into the output water stream, which in turn would be transmitted to the patients during oral surgical procedures. Thus, as a result of its inherent design, practitioners could not safely use the Cavitron, or satisfy state regulations or CDC guidelines, during the performance of oral surgical procedures. Further, the complaint states that appellants were not aware of the biofilm health risk when they purchased their Cavitrons, and Dentsply was aware of but concealed and misrepresented the critical facts.

All Cavitrons, except the "Select" model, are designed to be plumbed to an external municipal water source. Appellants presented evidence that to render Cavitrons safe for surgical use, the practitioner should acquire an alternate system designed to avoid waterline contamination, for example a self-contained water system. Even if the input water is sterile, it must flow past and through the Cavitron's inner tubing, which has a very fine diameter of one to two millimeters, is not sterile and cannot be sterilized. Thus, regardless of the input water source, the Cavitron cannot reliably deliver sterile output water for surgical applications. In addition, although the Directions recommend flushing the waterline as a routine maintenance procedure, flushing with water does not remove biofilm.

Indeed, following discovery in this case, in June 2005 Dentsply sent letters to over 20,000 California dentists emphasizing that "conventional ultrasonic scalers do not deliver sterile fluids unless specifically equipped with a sterile water delivery system. Therefore, if in your professional judgment, any dental procedure requires the delivery of sterile fluids, choose a sterile delivery system." And, beginning with the release of the 2006 Cavitron model, the accompanying Directions added a warning advising against the

use of the product where asepsis[7] is required or deemed appropriate. Further, the Directions for the first time "strongly recommended" that the waterlines be flushed weekly with a sodium hypochlorite (bleach).

The complaint divided the proposed class into two subclasses: Subclass A consisted of members who purchased the Cavitron prior to 1999 for use "in the performance of oral surgical applications as to which Dentsply's accompanying [Directions] specified that it was indicated for use for root planing during oral surgery." Subclass B consisted of those who purchased the device in or after 1997 for use in such procedures, and for which the accompanying Directions stated that the device "was indicated for 'periodontal debridement for all types of periodontal diseases.' "

Appellants pursued certification of the proposed class as to each cause of action. Initially, the trial court approved classes for the UCL and express warranty claims.

Shortly thereafter, the Second District Court of Appeal issued its opinion in *Pfizer, Inc. v. Superior Court* (2006) 141 Cal.App.4th 290, review granted November 1, 2006, S145775, and cause transferred to Court of Appeal, Second Appellate District, Division Three, with directions to vacate its decision and reconsider in light of *Tobacco II*, *supra*, 46 Cal.4th 298 (*Pfizer*). *Pfizer* addressed the impact of Proposition 64 on class action standing requirements. The court held that *all* class members must suffer injury in fact and lose money or property as a result of the unfair competition or false advertising. Further, as an inherent aspect of this requirement, in entering the transaction at issue, the plaintiffs necessarily must have relied on the false or misleading representation or advertisement.

Relying principally on *Pfizer*, Dentsply moved to decertify appellants' UCL claim and further argued that the court's analysis in *Pfizer* and controlling case law should compel decertification of the breach of warranty claims as well. The trial court agreed, ruling as to the UCL cause of action that each class member would have to prove

[7] Asepsis is the "condition of being asceptic," i.e., free "from pathogenic microorganisms." (Merriam-Webster's Collegiate Dict. (10th ed. 2001) p. 67 [definitions for "aseptic" and "asepsis"].)

standing under Proposition 64, a hurdle mandating individual proof of financial damage caused by reliance on the material false representation. Thus, individual issues relating to materiality, reliance and resulting damage would predominate, rendering the UCL claim inappropriate for class treatment. As well, proving causation would entail inquiry into whether each class member saw, read and relied on the alleged misrepresentation in deciding to purchase a Cavitron, yet another individual inquiry.

The trial court proceeded also to decertify the class as to the breach of express warranty claims, notwithstanding that there were no changed circumstances and no newly discovered evidence. Instead, based on existing law that predated the original certification motion, and obviously influenced by the *Pfizer* decision, the trial court ruled that (1) appellants could not prove reliance on Dentsply's alleged misrepresentations on a classwide basis; although reliance could be presumed under some circumstances, the presumption was rebuttable and use of the class procedure would circumvent Dentsply's right to rebut; and (2) variations in the wording of the Directions for the different Cavitron models created predominantly individual fact issues concerning reliance, so the court could not infer classwide reliance.

Appellants moved for reconsideration of the decertification order in October 2006. While the motion was under review, our Supreme Court granted review in *Pfizer* and *In re Tobacco II Cases* (2006) 142 Cal.App.4th 891. The trial court requested briefing on the propriety of staying the matter pending resolution of those cases. However, based on subsequent submissions the court withdrew its request and denied the motion for reconsideration. This appeal followed.

II. DISCUSSION

A. *Decertification of UCL Cause of Action*

Post-Proposition 64, the UCL provides: "Any person may pursue representative claims or relief on behalf of others only if the claimant meets the standing requirements of [Business and Professions Code] Section 17204 and complies with Section 382 of the Code of Civil Procedure . . . ." (Bus. & Prof. Code, § 17203, as amended by Prop. 64, § 2.) In turn, section 17204 permits actions for relief under the UCL to be prosecuted by

"a person who has suffered injury in fact and has lost money or property as a result of the unfair competition." (Bus. & Prof. Code, § 17204, as amended by Prop. 64, § 3.)

In *Tobacco II*, our Supreme Court rejected the rationale that informed the trial court's decertification order. First, it held that Proposition 64's standing requirements for UCL actions apply only to the class representatives. (*Tobacco II*, *supra*, 46 Cal.4th at p. 306.) Second, the standing requirements as modified by Proposition 64 impose an actual reliance requirement on representative plaintiffs prosecuting a private enforcement action under the fraud prong of the UCL. (*Id.* at p. 326.) Further, while only the class representative need establish personal reliance on the defendant's misrepresentation or nondisclosure resulting in damage, the representative need not show that such reliance was " ' "the sole or even the predominant or decisive factor in influencing his conduct. . . . It is enough that the representation has played a substantial part, and so has been a substantial factor, in influencing his decision." [Citation.] [¶] Moreover, a presumption, or at least an inference, of reliance arises wherever there is a showing that a misrepresentation was material. [Citations.]' " (*Id.* at pp. 326-327.) A misrepresentation is "material" if a reasonable person would attach importance to its existence or nonexistence in deciding his or her course of action in the transaction in question. (*Id.* at p. 327.) Finally, the class representative need not demonstrate individualized reliance on a specific misrepresentation. (*Ibid.*)

We requested, and received, supplemental briefing on the impact and import of *Tobacco II* on the present appeal. Appellants argue without reservation that *Tobacco II* compels reversal of the decertification order, while Dentsply suggests a summary reversal with directions that the trial court evaluate the UCL certification anew in light of *Tobacco II*.[8]

[8] Dentsply took a different tack at oral argument, asserting instead that we should affirm the UCL decertification order because *one* of the trial court's UCL decertification rulings was untainted by Proposition 64 standing concerns, namely the ruling that the UCL claims were inappropriate for class treatment because individual issues about the nature and extent of any material misrepresentation would predominate over common issues. (*Kaldenbach v. Mutual of Omaha Life Ins. Co.* (2009) 178 Cal.App.4th 830, 844

Unlike the general rule compelling a reviewing court to scrutinize the *result* below, not the trial court's rationale, we analyze the propriety of an order denying class certification based solely on the lower court's stated reason for the decision. (*Bartold v. Glendale Federal Bank* (2000) 81 Cal.App.4th 816, 828-829, superseded by statute on another point as stated in *Markowitz v. Fidelity Nat. Title Co.* (2006) 142 Cal.App.4th 508, 524.) Thus we review only the reasons advanced by the trial court and ignore any

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[order denying class certification must be upheld if any of trial court's stated reasons are sufficient to justify order].) The court also noted that dentists typically did not see the Directions until after they purchased the Cavitron, and thus the Directions could not have influenced their purchasing decision.

First, procedurally this ruling was improper because Dentsply offered no new law or newly discovered evidence regarding the nature and extent of any material misrepresentation. (See *post*, pt. II.B.2.) Second, the ruling was substantively wrong.

The UCL prohibits as unfair competition "any unlawful, unfair or fraudulent business act or practice . . . ." (Bus. & Prof. Code, § 17200.) The act focuses on the *defendant's conduct,* rather than the plaintiff's damages, in keeping with its larger purpose of protecting the general public against unscrupulous business practices. (*Tobacco II*, *supra*, 46 Cal.4th at p. 312.) This case involves alleged uniform fraudulent practices—misrepresentations regarding the Cavitron's safety for surgical use and the concomitant nondisclosure of biofilm risk—by Dentsply, directed to the entire class. To sustain a UCL cause of action based on such fraudulent or deceptive practices, a plaintiff must show that " ' "members of the public are likely to be deceived." ' " (*Aron v. U-Haul Co. of California* (2006) 143 Cal.App.4th 796, 806, quoting *Committee on Children's Television, Inc. v. General Foods Corp.* (1983) 35 Cal.3d 197, 211; *Massachusetts Mutual Life Ins. Co. v. Superior Court* (2002) 97 Cal.App.4th 1282, 1291; accord, *Kaldenbach v. Mutual of Omaha Life Ins. Co.*, *supra*, 178 Cal.App.4th at p. 847.)

A plaintiff's burden thus is to demonstrate that the representations or nondisclosures in question would likely be misleading to a reasonable consumer. (See *Aron v. U-Haul Co. of California*, *supra*, 143 Cal.App.4th at p. 807.) The question of materiality, in turn, is whether a reasonable person would attach importance to the representation or nondisclosure in deciding how to proceed in the particular transaction—in other words, would a reasonable dentist attach importance to Dentsply's claim that the Cavitron was safe for use in surgery. (*Tobacco II*, *supra*, 46 Cal.4th at p. 327.) The safety of the Cavitron would be material to *any* dentist regardless of when the representation was made. The materiality of Dentsply's representations concerning the Cavitron's safety for surgical uses was established objectively by appellants' actual use of the device for oral surgery, in accordance with those representations, regardless of whether appellants saw the Directions before or after purchasing the device. There are no individual issues concerning the nature and extent of material misrepresentations.

other grounds which might support denial. (*Bartold v. Glendale Federal Bank*, *supra*, 81 Cal.App.4th at p. 829.) In other words, even if substantial evidence supports the decision denying certification, we will reverse if it is based on improper criteria or incorrect legal assumptions. (*Linder v. Thrifty Oil Co*. (2000) 23 Cal.4th 429, 435; *Capitol People First v. State Dept. of Developmental Services* (2007) 155 Cal.App.4th 676, 689.)

Here it is abundantly clear that the trial court incorrectly believed that each class member must establish standing, thereby requiring the court to delve into individual proof of material, reliance and resulting damage. *Tobacco II* has dispatched that reasoning and therefore reversal is appropriate.

In advocating summary reversal with remand and directions, Dentsply is of a mind that the trial court would still have to consider whether, under *Tobacco II*, the class representatives themselves can meet Proposition 64's standing requirements, a matter not decided by the trial court. In fact, the *Tobacco II* court reversed and remanded for further proceedings to determine whether the plaintiffs could establish standing as delineated by the opinion and, if not, whether amendment should be allowed. (*Tobacco II*, *supra*, 46 Cal.4th at p. 329.)

Ordinarily, the remedy of summary reversal is limited to situations where the proper resolution of the appeal is so obvious and without dispute that briefing would not serve any useful purpose. (See *Melancon v. Walt Disney Productions* (1954) 127 Cal.App.2d 213, 215.) Such a remedy allows for speedy determination of the appeal. (*Ibid*.) Here of course the parties have fully briefed the appeal. However, in the service of judicial economy by speedy determination of the propriety of decertification of the UCL class, we reverse that aspect of the order without further analysis or ado in light of the trial court's indisputably erroneous reasons for decertification. We remand for the limited purpose of determining whether the named representatives can meet the UCL standing requirements announced in *Tobacco II* and if not, whether amendment should be permitted.

B. *Breach of Express Warranties*

1. *Introduction; Standard of Review*

The third amended complaint alleged causes of action for breach of warranty as to each subclass, based on two categories of written express warranties. First, Dentsply expressly warranted at the time of purchase that the Cavitron "would be free from any defects in materials or workmanship that could affect its intended professional use in a dental office, for one year after its sale." Second, Dentsply expressly warranted that the device was "safe, appropriate and 'indicated' for use in performing root planing during oral surgical procedures" (class A members) and "all subgingival scaling, periodontal debridement of all types and endodontic procedures" (class B members). The express warranties were material to class members' decision to purchase and use the Cavitron, but the device was medically unsafe for their intended uses and thus Dentsply breached their express warranties.

Decertifying the breach of warranty class, the trial court in effect reassessed the matter under existing law, coupled with newly packaged, but not newly discovered, evidence. We conclude the trial court erred in decertifying the breach of warranty class.

Code of Civil Procedure section 382 allows class actions "when the question is one of a common or general interest, of many persons, or when the parties are numerous, and it is impracticable to bring them all before the court . . . ." The question of certification does not delve into whether the action is factually or legally meritorious. Instead, the advocate for certification must establish the existence of a well-defined community of interest among the class members. The community of interest requirement embraces three components: (1) common questions of law or fact that predominate over questions affecting individual members; (2) class representatives whose claims or defenses are typical of the class; and (3) class representatives who can adequately represent the class. (*Lockheed Martin Corp. v. Superior Court* (2003) 29 Cal.4th 1096, 1104; *Capitol People First v. State Dept. of Developmental Services, supra,* 155 Cal.App.4th at pp. 688-689.)

Trial courts enjoy broad discretion in granting or denying class certification because they are ideally positioned to evaluate the efficiencies and practicality of group action. (*Linder v. Thrifty Oil Co., supra*, 23 Cal.4th at p. 435.) However, this latitude in ruling on certification matters does not encompass discretion to misstate or misapply the law. Thus we will not overturn the lower court's certification decision which is supported by substantial evidence unless it relied on improper criteria or made erroneous legal assumptions. (*Id.* at pp. 435-436; *Bufil v. Dollar Financial Group, Inc*. (2008) 162 Cal.App.4th 1193, 1204-1205.)

2. *No New Evidence or Law*

Rule 3.764(a)(4) of the California Rules of Court provides that any party may file a motion to decertify a class. Our Supreme Court has recognized that trial courts should retain some flexibility in conducting class actions, which means, under suitable circumstances, entertaining successive motions on certification if the court subsequently discovers that the propriety of a class action is not appropriate. (*Occidental Land, Inc. v. Superior Court* (1976) 18 Cal.3d 355, 360.) There, following class certification, the defendant conducted discovery and moved for decertification based on newly discovered evidence. (*Ibid.*) However, based on all the circumstances, the court concluded that the trial court did not abuse its discretion in refusing to decertify the class. (*Id.* at p. 363.) In *Green v. Obledo* (1981) 29 Cal.3d 126, our state's high court focused on the propriety of decertification *after* a decision on the merits. The court observed that *prior to* judgment "a class should be decertified 'only where it is clear there exist changed circumstances making continued class action treatment improper.' [Citation.] A fortiori, a similar showing must be made to warrant decertification after a decision on the merits. This standard will prevent abuse on the part of the defendant while providing the trial court with enough flexibility to justly manage the class action." (*Id.* at p. 148 & fn. 17.) In that case, the court pointed out that the belated motion was not based on changed circumstances, nor did the defendant adduce new evidence. (*Id.* at p. 148.)

Dentsply is adamant that there is no requirement of changed circumstances or new evidence when the trial court revisits certification prior to a decision on the merits. The

dicta in *Green v. Obledo, supra,* 29 Cal.3d 126, quoted above, concerning prejudgment decertification, would suggest otherwise. The standard announced in *Green* allows flexibility while curtailing defendant abuse. In the case at hand, Dentsply's motion for decertification was accompanied by changed circumstances, most notably the *Pfizer* decision. However, this circumstance only pertained to the UCL cause of action. Nevertheless, the trial court went on to address Dentsply's reassertions as to why the breach of warranty class should be decertified as well. Decertifying one theory should not sanction decertifying another absent some commonality with the changed circumstance or some other situation justifying reconsideration. Here there was none.

In any event, as we discuss, even if the trial court correctly reconsidered its certification of the breach of warranty class, its substantive decision was wrong.

3. *Reliance*

The lower court ruling rests on the incorrect legal assumption that a breach of express warranty claim requires proof of prior reliance. While the tort of fraud turns on inducement, as we explain, breach of express warranty arises in the context of contract formation in which reliance plays no role.

Section 2313, subdivision (1)(a) and (b) of the California Uniform Commercial Code[9] governs this cause, providing that express warranties are created as follows: "(a) Any affirmation of fact or promise made by the seller to the buyer which relates to the goods and becomes part of the basis of the bargain creates an express warranty that the goods shall conform to the affirmation or promise. [¶] (b) Any description of the goods which is made part of the basis of the bargain creates an express warranty that the goods shall conform to the description." Hence, to prevail on a breach of express warranty claim, the plaintiff must prove (1) the seller's statements constitute an " 'affirmation of fact or promise' " or a " 'description of the goods' "; (2) the statement was " 'part of the basis of the bargain' "; and (3) the warranty was breached. (*Keith v. Buchanan* (1985) 173 Cal.App.3d 13, 20 (*Keith*).)

[9] All further statutory references are to the California Uniform Commercial Code.

Pre-Uniform Commercial Code law governing express warranties required the purchaser to prove reliance on specific promises made by the seller. (*Hauter v. Zogarts* (1975) 14 Cal.3d 104, 115, referencing *Grinnell v. Charles Pfizer & Co*. (1969) 274 Cal.App.2d 424, 440.) The Uniform Commercial Code, however, does not require such proof. Instead, the official comment to section 2313 explains that "[i]n actual practice affirmations of fact made by the seller about the goods during a bargain are regarded as part of the description of those goods; hence no particular reliance on such statements need be shown in order to weave them into the fabric of the agreement. Rather, any fact which is to take such affirmations, once made, out of the agreement requires clear affirmative proof." (Cal. U. Com. Code com., 23A pt. 1 West's Ann. Cal. U. Com. Code (2002 ed.) foll. § 2313, com. 3, p. 296.) The statute thus creates a presumption that the seller's affirmations go to the basis of the bargain. In light of the language of section 2313 and official comment 3, the court in *Keith* concluded that "the concept of reliance has been purposefully abandoned." (*Keith*, *supra*, 173 Cal.App.3d at p. 23.)

The phrase "part of the basis of the bargain" is obscure at best and its effect has generated significant comment and disagreement. (See *Hauter v. Zogarts*, *supra*, 14 Cal.3d at pp. 115-116 [noting disagreement but declining to resolve whether basis of bargain requirement eliminates reliance altogether]; Hodaszy, *Express Warranties Under the Uniform Commercial Code: Is There a Reliance Requirement?* (1991) 66 N.Y.U. L.Rev. 468.) The term "bargain" is not specifically defined in the Uniform Commercial Code but is integral to the definition of "agreement," which refers to "the bargain of the parties in fact, as found in their language or inferred from other circumstances, including course of performance, course of dealing, or usage of trade . . . ." (§ 1201, subd. (b)(3).) In turn the "contract" is "the total legal obligation that results from the parties' agreement as determined by this code and as supplemented by any other applicable of laws." (§ 1201, subd. (b)(12).)

Quoting from official comment 1[10] to section 2313, Dentsply argues that seller's affirmations or descriptions concerning the goods become express warranties only if they were part of the " ' "dickered" aspects of the individual bargain,' '' and thus only representations that actually reach the buyer *before* the purchase is consummated can become part of the " 'basis of the bargain.' " Here it is undisputed that the alleged express warranties are statements in the Directions, and the Directions are sealed in the Cavitron package when delivered.

Dentsply relies on *Cuthbertson v. Clark Equipment Co*. (Me. 1982) 448 A.2d 315, 321 for the proposition that representations in a user manual are not express warranties where the purchaser does not see the manual or dicker over its language prior to purchase. Specifically, Dentsply reasons that because the Directions were not available until delivery and the "purchase decision had already been made," appellants cannot prove that they saw and read the statements prior to the purchase and thus their breach of express warranties claims are doomed. Not so.

To begin with, the obvious purpose of comment 1 is to compare express and implied warranties. Moreover, the "whole purpose" of warranty law is "to determine what it is that the seller has in essence agreed to sell . . . ." (Cal. U. Com. Code com., 23A pt. 1 West's Ann. Cal. U. Com. Code, *supra*, foll. § 2313, com. 4, p. 296; *Keith*, *supra*, 173 Cal.App.3d at p. 20.) Therefore, in keeping with this purpose, section 2313 focuses on *the seller's* behavior and obligation—his or her affirmations, promises, and descriptions of the goods—all of which help define what the seller "in essence" agreed to sell. While not binding, the Supreme Court of Oregon has persuasively tied the statements inhering to the basis of the bargain to the "essence" of what the seller agrees

[10] Comment 1 states in part: " 'Express' warranties rest on 'dickered' aspects of the individual bargain, and go so clearly to the essence of that bargain that words of disclaimer in a form are repugnant to the basic dickered terms. 'Implied' warranties rest so clearly on a common factual situation or set of conditions that no particular language or action is necessary to evidence them and they will arise in such a situation unless unmistakably negated." (Cal. U. Com. Code com., 23A pt. 1 West's Ann. Cal. U. Com. Code, *supra*, foll. § 2313, com. 1, p. 296.)

to sell, explaining as follows: "The basis of the bargain requirement . . . does not mean that a description by the Seller must have been *bargained for*. Instead, the description must go *to the essence of the contract*." (*Autzen v. John C. Taylor Lbr. Sales, Inc*. (Or. 1977) 572 P.2d 1322, 1326; see also *Alan Wood Steel Co. v. Capital Equip. Enter. Inc*. (Ill.App. 1976) 349 N.E.2d 627, 632 ["[t]he 'basis of the bargain' test focuses upon the descriptions or affirmations which clearly go to the essence, or the basic assumption, of the bargain between the parties"].)

As well, we point out that while the basis of the bargain of course includes dickered terms to which the buyer specifically assents, section 2313 itself does not suggest that express warranty protection is confined to them such that affirmations by the seller that are not dickered are excluded. Any affirmation, once made, is part of the agreement unless there is "clear affirmative proof" that the affirmation has been taken out of the agreement. (See Cal. U. Com. Code com., 23A pt. 1, West's Ann. Cal. U. Com. Code, *supra*, foll. § 2313, com. 3, p. 296.)

It is also important to recognize that the Directions represent Dentsply's compliance with federal labeling obligations. As to any given Cavitron model that a dentist may purchase, Dentsply has already prepared the Directions and they are included within the packaging of the device upon delivery. *Thus, any descriptions or affirmations about the Cavitron contained in the Directions have already been made by Dentsply at the time the product is delivered to the consumer*. The Directions and statements and descriptions therein therefore are part of what the buyer bought and the seller "in essence agreed to sell . . . ." (Cal. U. Com. Code com., 23A pt. 1 West's Ann. Cal. U. Com. Code, *supra*, foll. § 2313, com. 4, p. 296.) Indeed, the furnishing of federally mandated Directions could be viewed as a "usage of trade" or "other circumstances" informing the "bargain of the parties" or the making of the "[a]greement." (§ 1201, subd. (b)(3).) Under the Uniform Commercial Code, "usage of trade" is "any practice or method of dealing having such regularity of observance in a place, vocation, or trade as to justify an expectation that it will be observed with respect to the transaction in question." (§ 1303, subd. (c).) Without question, a dental professional would expect that the Directions

would accompany the class 2 medical device, and that the device would be safe for the uses indicated therein. Likewise, part of the "other circumstances" framing any transaction to purchase a Cavitron is the fact that federal law requires Dentsply to provide labeling with indications for use and other product information. Thus, as inferred from these "other circumstances," the Directions became part of the "agreement" or "bargain of the parties" as set forth in section 1201, subdivision (b)(3).

Under Dentsply's view of express warranty law, the company would not be obliged to stand by any statement it made in the Directions, including the printed "limited warranty" guaranteeing against defects in manufacture and workmanship. Surely this is not the law. As one sister state court has put it convincingly, although "the warranty was technically handed over *after* plaintiffs paid the purchase price, the fact that it was given to plaintiffs at the time they took delivery of the [product] renders it sufficiently proximate in time so as to fairly be said to be part of the basis of the bargain [citations]. To accept the manufacturer's argument that in order to be part of the basis of the bargain the warranty must actually be handed over during the negotiation process so as to be said to be an actual procuring cause of the contract, is to ignore the practical realities of consumer transactions wherein the warranty card generally comes with the goods, packed in the box of boxed items . . . . Indeed, such interpretation would, in effect, render almost all consumer warranties an absolute nullity." (*Murphy v. Mallard Coach Co*. (N.Y.App.Div. 1992) 179 A.D.2d 187, 193 [582 N.W.S.2d 528, 531]; accord, *Rite Aid v. Levy-Gray* (Md.Ct.App. 2006) 894 A.2d 563, 573-574; *In re Bridgestone/Firestone Inc. Tires Products* (S.D.Ind. 2001) 205 F.R.D. 503, 527 & fn. 31, revd. on other grounds in *In re Bridgestone/Firestone, Inc.* (7th Cir. 2002) 288 F.3d 1012.)

The official comment to section 2313 is also instructive on this point, providing: "The precise time when words of description or affirmation are made . . . is not material. The sole question is whether the language . . . [is] fairly to be regarded as part of the contract." (Cal. U. Com. Code com., 23A pt. 1 West's Ann. Cal. U. Com. Code, *supra*, foll. § 2313, com. 7, p. 297.) Thus, the Uniform Commercial Code contemplates that affirmations, promises and descriptions about the goods contained in product manuals

and other materials that are given to the buyer at the time of delivery can become part of the basis of the bargain, and can be "fairly . . . regarded as part of the contract," notwithstanding that delivery occurs after the purchase price has been paid. (*Ibid*.)

We further note that under the Uniform Commercial Code, the "agreement," or "bargain of the parties" is distinguishable from the "contract," such that the legal formation of the contract need not be the final resting point beyond which affirmations can no longer become part of the basis of the bargain. Instead, as the *Autzen* court put it, the term "bargain" as used in the Uniform Commercial Code " 'describes the commercial relationship between the parties in regard to [the] product. . . . The . . . "bargain" [is] a process which can extend beyond the moment in time that the offeree utters the magic words, "I accept".' [Citation.]" (*Autzen*, *supra*, 572 P.2d at p. 1325 [bargain was still in progress when seller-commissioned survey of boat in question was performed; survey occurred day *after* purchase price was agreed upon, but before time for payment and transfer of possession were settled, and stated results of survey constituted express warranty].)

Finally, the notion of "good faith" which infuses the Uniform Commercial Code affords another rationale for recognizing the validity of express warranties delivered with the purchased product. "Good faith" for purposes of the law of sales means "honesty in fact and the observance of reasonable commercial standards of fair dealing." (§ 1201, subd. (b)(20).) Additionally, every contract governed by the Uniform Commercial Code "imposes an obligation of good faith in its performance and enforcement." (§ 1304.) Even before purchasing a product, a buyer would reasonably expect any statement or description of the product appearing in a user manual or similar publication to be true, regardless of when the manual was received or read. A seller's defense based solely on the postsale timing of receipt or awareness of the manual arguably would fall short of good faith.

4. *Variations in Directions*

The trial court further found that since 1993, approximately 30 different Directions have been published and supplied with Cavitrons. And, in addition to the "Indications"

for use, "Contraindications and Warnings" and "Precautions," the various Directions referenced other recommendations, guidelines, CDC and American Dental Association standards, and warnings and admonitions, such as the infection control information card.[11] Thus, because these Directions were not uniform, the court ruled it could not infer classwide reliance and instead would have to examine each Direction to determine the scope of the representation and whether there was reasonable reliance by each class member on such representation.

First, as we have already discussed, the trial court incorrectly assumed that reasonable reliance was an element of the breach of express warranty claim that each member would have to establish. In support of this ruling the trial court cited *Osborne v. Subaru of America, Inc*. (1988) 198 Cal.App.3d 646, 661 (*Osborne*). *Osborne* is not convincing authority. The *Osborne* court affirmed denial of certification to a *nationwide* class raising claims of strict liability, fraud, negligent misrepresentation, negligence, and breach of implied and express warranty. The *Osborne* litigation manifested a host of problems not present in the instant case which factored into the court's unwillingness to certify a nationwide class, including ponderable conflict of laws issues, a huge potential putative class of owners of approximately 180,000 automobiles and the infeasibility of creating an acceptable number of subclasses. (*Id.* at p. 651.) Moreover, the purported warranty representations were based on a national advertising campaign. (*Id*. at p. 660.) Further, although the *Osborne* court stated that there was no basis to infer classwide reliance without a showing that the representations were made uniformly to all class members, this statement was made *generally* as to the express warranty, fraud and negligent misrepresentation claims, backed by citation to cases addressing the element of reliance *for fraud*. (*Id*. at pp. 660-661.) There was no independent analysis of the elements of breach of express warranty, and significantly, no mention of *Keith*.

[11] This card advised that its purpose was "to supplement published general guidelines for reducing cross contamination of infectious diseases when using a [Cavitron] during routine dental care. In the event any regulatory agency disagrees with this information, the agency requirements take precedence."

More importantly, the finding that the Directions were not uniform does not imply that the variations were material to the claims of the two subclasses. Indeed, the trial court did not address the issue of materiality. Within the two subclasses, there was no possibility for variation among the representations at issue because the two subclasses were defined by the appropriate wording that the Cavitron was medically indicated for surgical use: Specifically, as to subclass A the representation was that the Cavitron was indicated for use for "root planing during oral surgery," whereas the pertinent subclass B representation specified that the device was indicated for " 'periodontal debridement for all types of periodontal diseases.' " Dentsply did not, and has not, identified any variation in the wording of indications for use, contraindications, precautions or maintenance instructions within the models contained in the two subclasses that bear materially on the issues relevant to the lawsuit. Significantly, throughout the class period, the Directions were silent on the issue of biofilm infection risk.

Additionally, the infection control information card is a red herring, notwithstanding Dentsply's assertion that it contained warnings contradicting the indications for use. Other than advising on brief flushing of waterlines at the beginning of the day and between patients, the bulk of the "information" on the card pertained to cleaning the Cavitron's external surfaces and sterilizing removable patient-contact components. The card did not mention waterline biofilm risk or its treatment, nor did it discuss the indications for use. Thus no information relevant to this litigation was identified on the card with which an agency could "disagree" such that its regulations contradicted, and would take precedence over, the Directions. The vague statement that in the event of a disagreement agency requirements would trump the Directions has no context and therefore should not doom the class action. We further point out that the statement quoted in footnote 11, *ante*, was identical throughout the subclass periods for all models.

Nonetheless Dentsply suggests that a dentist who received the infection control information card could not "reasonably rely" on any statement in the Directions about the Cavitron's propriety for use in surgical procedures, reasoning that California regulations

have required since the mid-1990's that sterile water be used during such procedures, and appellants are not alleging they understood the Cavitron was capable of producing sterile water. Although this statement is not particularly articulate, it appears Dentsply is arguing that an indication for surgical use would be contrary to California regulations, and thus the regulations would supplant any warranties in their product inserts, and such warranties would in effect go away.

Dentsply cannot circumvent responsibility for its warranties in the guise of a conflict with governing regulations. To begin with, the infection control information card sets forth supplemental guidelines, in the form of recommended daily procedures for reducing contamination when using the Cavitron. The card does not address *the very purpose* of the device, as gleaned from the indicated uses. Thus, any agency's "disagreement" would be with the propriety of a particular maintenance procedure.

Further, while we agree that appellants do not claim Dentsply warranted that the Cavitron produced a specific quality of water or promised sterility, this state of affairs does not help Dentsply. Appellants proclaim that Dentsply warranted the Cavitrons were free from defects in workmanship and materials that would pose health risks to patients, and were safe and indicated for use in surgical applications when maintained as specified in the Directions. The alleged inevitable formation of biofilm is both the inherent defect in the Cavitron, as well as the health risk that purportedly renders the device unsafe. Appellants' evidence showed that regardless of the quality of input water and adherence to recommended maintenance protocols, the output water was contaminated due to the biofilm and thus unsafe for use in surgical applications. This was so because the Cavitron's permanent untreatable plastic inner tubing formed and released bacteria into dental water, rendering the device unsafe.

Dentsply further asserts that it was not an abuse of discretion for the trial court to determine that statements in the Directions relied on by plaintiffs could not be divorced from the "shifting factual context" in which they appeared. This generalized complaint does not advance Dentsply's cause. Neither Dentsply nor the trial court have identified a material change in the factual context, whether it be the actual wording in the Directions,

changes in regulations or standards, or the like, that affected the material issues in this lawsuit.

Further, the CDC guidelines and American Dental Association standards did not countermand Dentsply's recommended maintenance practices. Interestingly, the CDC guidelines refer the practitioner to the manufacturer for "the best method for maintaining acceptable water quality . . . ."

5. *Seller's Right to Rebut*

The *Keith* court explained that a buyer's actual knowledge of the true condition of the goods prior to making a contract "may make it plain that the seller's statement was not relied upon as one of the inducements for the purchase . . . ." (*Keith, supra*, 173 Cal.App.3d at p. 23.) For example, where a buyer inspects goods prior to the purchase, he or she may be deemed to have waived any express warranties, thereby discharging the seller from such warranties. However, in these circumstances it is up to the seller to demonstrate the buyer's prior knowledge, the scope of examination or inspection, what was actually discovered, and the like. (*Id*. at pp. 23-24.) Here the trial court honed in on and expanded this holding into a barrier to class certification. The court reasoned that if a class member did not receive the product literature until after purchasing the product, Dentsply could rebut the "presumption of reliance." Additionally, the court posited that if a class member purchased a Cavitron for nonsurgical uses and later decided to use it in surgery, the representation that the device was indicated for surgical use could not become part of the basis of the bargain.

The court misunderstood the scope of the seller's right to rebut. First, as we have demonstrated, affirmations and descriptions in product literature received at the time of delivery but after payment of the purchase price are, without more, part of the basis of the bargain, period. Second, the seller's right to rebut goes to proof that extracts the affirmations from the "agreement" or "bargain of the parties in fact," not, as *Keith* would

suggest, to proof that they were not an inducement for the purchase.[12] Relying on *Keith*, the court in effect equated the concept of the "bargain in fact of the parties" with the concept of reliance, but as we detailed above, the two are not synonymous. Moreover, the opinion in *Keith* contradicts itself on this matter. On the one hand the opinion states unequivocally that "[i]t is clear" section 2313 "purposefully abandoned" the concept of reliance. (*Keith, supra,* 173 Cal.App.3d at p. 23.) On the other hand, we must ask if section 2313 has eliminated the concept of reliance from express warranty law all together, by what logic can reliance reappear, by its absence, as an affirmative defense?

To reiterate, once affirmations have been made, they are woven into the fabric of the agreement and the seller must present "clear affirmative proof" to remove them from the agreement. (Cal. U. Com. Code com., 23A pt. 1 West's Ann. Cal. U. Com. Code, *supra,* foll. § 2313, com. 3, p. 296.) Since the purpose of warranty is to resolve what the seller "in essence agreed to sell," the representation that a product is safe for a certain use would be viewed as part of the description of the product going to the essence of the agreement and ultimate contract. Hence the representation would not lose express warranty status simply because the buyer initially bought the device with another use in mind.

In any event, the trial court's concern that class procedures would circumvent Dentsply's rebuttal rights is unfounded. We agree, as a general principle, that a defendant may defeat class certification by demonstrating that "an affirmative defense would raise issues specific to each potential class member and that the issues presented by that defense predominate over common issues." (*Walsh v. IKON Office Solutions, Inc*. (2007) 148 Cal.App.4th 1440, 1450.) However, the possibility that a defendant may be able to defeat the showing of an element of a cause of action "as to a few individual class members[,] does not transform the common question into a multitude of individual

[12] In a similar vein, we note that CACI No. 1240, which Dentsply discusses, is appropriately titled "Affirmative Defense to Express Warranty—Not 'Basis of Bargain.' " However, citing *Keith* as a source, the instruction itself misguidedly states that the defendant is not liable for harm to the plaintiff if the defendant "proves that plaintiff did not rely on" the defendant's statement in deciding to purchase the product.

ones . . . ." (*Massachusetts Mutual Life Ins. Co. v. Superior Court* (2002) 97 Cal.App.4th 1282, 1292-1293.)

Dentsply "in essence agreed to sell" Cavitrons that came complete with federally mandated Directions indicating the device's use in surgical procedures. (Cal. U. Com. Code com., 23A pt. 1 West's Ann. Cal. U. Com. Code, *supra*, foll. § 2313, com. 4, p. 296.) The sale of Cavitrons is legally restricted to dentists and the subclasses, as defined, are confined to dentists in California who purchased the device for use in oral surgery. The issue is whether patient safety in surgical applications went to the essence of what Dentsply agreed to sell. Dentsply would be hard pressed to show it did not. Furthermore, there was no factual showing that the relevant affirmations were *taken out of* the agreement, i.e., there was no showing that any class members were not concerned about surgical safety or the safe functioning of Cavitrons according to their indicated uses, or waived affirmations going to such concerns.

Dentsply also suggests that it theoretically could meet its burden of rebutting any presumption that statements in the Directions created an express warranty by showing that individual class members knew that the Directions supposedly "were not accurate under applicable California regulations." This argument goes to the matter of water sterility. As we made clear above, the issue in this litigation is not water sterility per se, but rather the formation of bacteria-laden biofilm, caused by the design of the Cavitron's inner water tubing, and the contamination risks posed by that phenomenon. There was no evidence that appellants were aware of the biofilm risk posed by Cavitron usage, but purchased and used it anyway.

III. DISPOSITION

The order is reversed and remanded for the limited purpose of deciding whether the named representatives can meet the UCL standing requirements specified in *Tobacco II*, and if not, whether amendment should be permitted.

_____
Reardon, J.

We concur:

_____
Ruvolo, P.J.

_____
Rivera, J.

Trial Court:	San Francisco Superior Court
Trial Judge:	Hon. Ronald Evans Quidachay
Counsel for Appellants:	Duane Morris Bullivant Houser Bailey Paul D. Nelson
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